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Re: United States v. Reilly Tar & Chemical Corp.
No. 4-80-469 (D. Minn.)

Gentlemen:

This letter is to advise you of the fact witnesses whom the United States intends to call in this case and to identify the in-house employees who will testify about technical issues.

Fact Witnesses. The United States incorporates by reference the list of fact witnesses provided by the State of Minnesota. Because counsel for Reilly indicated at the discovery conference on January 9 that Reilly would stipulate to the authenticity and admissability of sampling data, the United States is not presently listing fact witnesses who would testify concerning the chain of custody for this sampling data. If the proposed stipulation is not executed, the United States preserves the right to call those witnesses. However, the United States will call Ted Wilhite to testify concerning the samples currently being taken and analyzed by Acurex Corporation and Pablo Huidrobro to testify about soil borings taken by GCA Corporation.

In House Technical Witnesses. The United States will call Paul Bitter and H. Christopher Grundler of EPA. Mr. Bitter and Mr. Grundler will testify concerning the Record of Decision ("ROD") selecting drinking water treatment for SLP wells 10 and 15 and EPA's remedial decision making process. Mr. Bitter and Mr. Grundler will testify concerning possible remedial measures for the drift, Platteville, St. Peter, Prairie du Chien-Jordan, Ironton-Galesville, and Mt. Simon-Hinckley aquifers, and about remedial measures for surficial contamination, and the EPA process of selecting a remedy. The testimony will cover the remedial investigation and feasibility study for the drift, Platteville and St. Peter aquifers. For a further description of the topics they will discuss, see section 5 of the expert witness statement of Dr. James Mercer. Mr. Bitter's testimony will focus on the technical issues involved in remedial decision making. Mr. Grundler's testimony will focus on the programmatic issues involved in the remedy selection process. Documents on which they will rely include: the National Contingency Plan, the ROD, the EPA Ambient Water Criteria Document for Polynuclear Aromatic Hydrocarbons, the Cooperative Agreements between EPA and the MPCA, the expert witnesses statements, the various studies identified in response to Reilly's Interrogatory No. 11 of its November 1, 1984 set, and the sampling data. They will be presented as summary witnesses.

The United States may also present the testimony of an additional in-house technical witness. The United States was approved for the first time by Mr. Schwartzbauer's letter of December 31, 1984 that Reilly intends to present the testimony of certain expert witnesses (Drs. Havender and Smith) to challenge the validity of EPA's Ambient Water Criteria Document for Polynuclear Aromatic Hydrocarbons ("PAH Criteria Document"). The PAH Criteria Document was promulgated pursuant to section 304(a) of the Federal Water Pollution Control Act ("FWPCA"), 33 U.S.C. §1314(a). Thus, the PAH Criteria Document is subject to judicial review only in accordance with the FWPCA and the Administrative Procedure Act ("APA"). In an action to review the PAH Criteria Document these statutes would bar the introduction of evidence which had not been presented before the Administrator of EPA in promulgating the PAH Criteria Document. Accordingly, the United States will move to exclude this testimony. However, should the court admit this testimony over the United States' objection, the United States will submit the testimony of a rebuttal witness explaining EPA's decision in promulgating the PAH Criteria Document. The summary of this witness' testimony is the PAH Criteria Document. The United States will identify this witness shortly.

Sincerely yours,

Assistant Attorney General
Land and Natural Resources Division

David Hird

David Hird, Attorney
Environmental Enforcement Section

cc: Francis X. Hermann
Robert Leininger
Elizabeth Maxwell
Paul Bitter
William Sierks
H. Christopher Grundler

terrogatories of October 18

INTERROGATORY NO. 1. Identify in detailed and specific scientific terms the criteria, or in the event that there is no established criteria, then identify the standards or guidelines or other measurements currently used to define the level of acceptable PAH concentrations in water and soil for what has been designated the Reilly Tar & Chemical site in St. Louis Park, Minnesota.

(a) identify the scientific basis for the PAH criteria, standards, guideline or other measurement employed at the above referenced site.

(b) Identify the date on which the criteria, standard, guideline or other measurement was promulgated.

(c) Identify in a chronological fashion the administrative procedures under which the PAH criteria, standard, guideline or other measurement was promulgated. This includes but is not limited to the dates of notices, public comment periods, hearings, etc.

(d) Identify both the state and federal agencies and any departments therein primarily responsible for establishing the PAH criteria, standard, guideline or other measurement.

(e) Identify all persons involved and their involvement in establishing the PAH criteria, standard guideline or other measurement.

(f) Identify who, within each state and federal agency, had responsibility and authority for establishing PAH criteria, standards, guidelines or other measurements

(g) Identify what procedures were used to recommend, review and authorize PAH criteria, standards, guidelines or other measurements.

(h) Identify all communications between state agencies, between federal agencies and between state and federal agencies regarding the establishment of the current PAH criteria, standard, guideline or other measurement.

(i) Identify all communications to consultants or other non-government employees regarding the establishment of PAH criteria, standards, guidelines, or other measurements.

INTERROGATORIES OF OCTOBER 18, 1984

Response to Interrogatory No. 1

Plaintiff, United States of America objects to this interrogatory as unduly burdensome and as requesting information protected by the attorney-client privilege, the work product doctrine, and because it intrudes upon the mental processes of administrative decision makers. Without waiving any objections, the United States responds as follows.

The question is based on defendant's misunderstanding of the claims raised by the United States in this action. This is not an action to enforce specified environmental standards. The United States is suing under Section 7003 of RCRA and Sections 106(a) and 107(a) of CERCLA. Section 7003 of RCRA and Section 106(a) of CERCLA are "emergency powers" provisions. As the Second Circuit recognized, "suits brought under the emergency powers provisions ... often involve technical evaluations relating to pollutants for which effluent levels have not been established." United States v. Hooker Chemicals & Plastics Corp., docket nos. 84-6110, 84-6112, slip op. at 25 (2d. Cir. November 15, 1984). Section 107(a) of CERCLA provides that the United States may recover all costs not inconsistent with the National Contingency Plan ("NCP"). The NCP does not prescribe specific clean-up standards. Rather, its calls for an ad hoc selection of a remedial measure "that is technologically feasible and reliable and which effectively mitigates and minimizes damage to and provides adequate protection of public health, welfare, or the environment". 40 C.F.R. §300.68(j). The Preamble to the NCP made clear that the selection of a remedy under CERCLA does not require the formal adoption and use

of environmental standards:

The system does not explicitly require that environmental standards be used in determining the appropriate extent of remedy. However, §300.68 does specify "environmental effects and welfare concerns" as one of the criteria to be considered in determining the appropriate extent of remedy. In some cases, this would allow EPA to consider applicable standards in selecting the appropriate remedy. It must be noted, however, that circumstances will frequently arise in which there are no clearly applicable standards. For instance, acceptable levels of hazardous substances in soil are not established, and there are no generally accepted levels for many other hazardous substances in other media. Even where there are standards for a particular substance, they may not be applicable to the conditions surrounding the release. Therefore, if the Plan included a rigid requirement that standards be met, it would obscure the real issue in many cases of how to adequately protect public health.

EPA cannot develop new standards for the hundreds of substances it will be confronted with in response actions. Not only is the requisite legal authority lacking in CERCLA, but such a task would also be enormous, costly and time-consuming, and would unduly hamper the clean-up of releases, which is CERCLA's primary mandate. Therefore, EPA has developed a system for decision making which has as its primary feature a reasoned process that contains a series of checks throughout to ensure that the decision-making process produces an effective remedy. The methodology emphasizes cost-effective, environmentally sound remedies which are feasible and reliable from an engineering standpoint.

47 Fed. Reg. 31180, 31185 (July 16, 1982). Thus, the remedial program proposed for this site is to be selected through a reasoned decision-making process concerning the unique facts of this site.

On June 6, 1984, Assistant Administrator Lee M. Thomas signed a record of decision ("ROD") selecting a drinking water treatment system for St. Louis Park wells 10 and 15. The ROD, which has been previously made available to Reilly, speaks for itself. The ROD establishes a target level of less than 2.8 nanograms per liter of carcinogenic polynuclear aromatic hydrocarbons ("PAH") and less than 280 nanograms per liter of other PAH. U.S. EPA selected that target of less than 2.8 nanograms per liter for carcinogenic PAH, using U.S. EPA's Ambient Water Quality Criteria for Polynulcear Aromatic Hydrocarbons (1980) (hereinafter "PAH Criteria Document"). The PAH Criteria Document uses dose-response information from scientific literature and mathematical modeling to determine levels of exposure representing a range from 10-5 to 10-7 health risk. The document did not recommend a particular risk level in that range as "acceptable". The model determined exposure limits for that range of risks using benzo(a)pyrene, one of the most potent carcinogens among the PAH's, as a benchmark for all carcinogenic PAH's. The PAH Criteria Document describes the scientific methodology it employed.

In the ROD, EPA used the figure of less than 2.8 nanograms per liter as a conservative target level for all carcinogenic PAH, because the PAH Criteria Document demonstrated that 2.8 nanograms per liter would present a 10-6 health risk for benzo(a)pyrene. The target figure of 2.8 nanograms per liter for all carcinogens would

be conservative because benzo(a)pyrene is one of the most potent carcinogens among the PAH's.

The target level for other PAH's was determined to be 280 nanograms per liter. As the ROD indicates, this figure was selected because the data at St. Louis Park wells 10 and 15 showed a ratio between the carcinogens and the total PAH of 0.007 to 0.01. Thus, a maximum level of 280 nanograms per liter for other PAH's would provide a conservative indicator for the presence of carcinogens in the drinking water, as well as protect against the interaction of the carcinogens and the other compounds among the other PAH's which may promote tumors.

A fuller discussion of the reasons for the selection of criteria is contained in the ROD and is incorporated by reference. The United States also identifies the documents listed in the administrative record, previously given to Reilly, documents upon which EPA relied in selecting operable criteria in the ROD.

As further support for the harmful effects of PAH's on health, the United States incorporates the expert witness statements of Dr. James Selkirk and Dr. Bertram Carnow, and the documents referenced therein, EPA Position Documents 2/3 and 4 on Creosote, and the documents referenced therein, Appendix I to the ERT report and the documents referenced therein, and R.D. Harbison's Coal Tar Products and Health Effects (1983) (attached).

The ROD was signed by Assistant Administrator Lee M. Thomas on June 6, 1982; the ROD was adopted pursuant to the National Contingency

Plan. The procedural history of the Assistant Administrator's selection of a remedial measure for St. Louis Park wells 10 and 15 is contained in the ROD and is incorporated herein by reference. In reaching this decision, Assistant Administrator consulted with members of his staff, counsel and Dr. James Selkirk. Mr. Paul Bitter, the EPA on-scene coordinator consulted with representatives of the Minnesota Pollution Control Agency in connection with the selection of a remedy. The United States objects to further inquiry into the decision making process for the reasons stated in its memorandum in support of a protective order to quash the notice of deposition of Lee Thomas.

SUBJECT: Toxicity Data for Polynuclear Aromatic Hydrocarbons: Reilly Tar Site in St. Louis Park, Minnesota

FROM: Charles Ris
Acting Executive Director
Carcinogen Assessment Group (RD-689)

TO: William N. Hedeman, Jr.
Director
Office of Emergency and Remedial Response (WH-548)

THRU: Elizabeth L. Anderson
Director
Office of Health and Environmental Assessment (RD-689)

Your April 18, 1984, memorandum requests carcinogenic and general toxicity data for Polynuclear Aromatic Hydrocarbons (PAH). On short notice the only cancer assessment data base that we can refer to is assessment data that was prepared for water quality criteria purposes in both 1980 and 1982. As for the availability of noncarcinogenicity toxicity for PAH's, there is one other compound for which noncarcinogenic health data exists and hence, a related criterion value.

CARCINOGENICITY

Out of the 13 PAH compounds on the list of 129 water quality priority pollutants, there are six PAH compounds which have qualitative evidence of being carcinogenic in experimental animals. One of these, benzo-a-pyrene (BaP), has adequate animal data for oral cancer potency estimation.

Chemical

1. Benzo-(a)-pyrene
2. Benzo-(b)-fluoranthene
3. Benzo-(a)-anthracene
4. Indeno-(1,2,3,-c,d)-pyrene
5. Dibenzo-(a,h)-anthrene
6. Chrysene

Our scan of new literature suggests that other PAH compounds have evidence

of carcinogenicity. We cannot, however, in this short time frame, offer an evaluation of this new data, except to say that the total number of compounds with carcinogenic evidence may increase to 12 or more.

Since there are no studies available regarding chronic oral exposure to PAH mixtures, it is necessary to derive carcinogenic potency factors and/or criteria levels using data on individual compounds, and thereafter, devise a method for using these potencies in a mixture situation. We have at the moment a potency factor estimate and a water quality criterion level based upon the potency of benzo-(a)-pyrene, (BaP). As referenced in the EPA Report 440/5-80-069 Ambient Water Quality Criteria for Polynuclear Aromatic Hydrocarbons dated October 1980, the carcinogenic potency factor of BaP for humans, based on an animal oral ingestion study, is:

$$q_1^* = 11.53 \text{ (mg/kg/day)}^{-1}.$$

Using this potency factor and the exposure assumption of ingesting 2 liters of water containing BaP, the concentrations of BaP contaminant and the corresponding to upper-limit risk levels of 10^{-5} to 10^{-7} is shown below. These vary slightly from the water quality criterion because the ingestion of contaminated fish is not included in this exposure consideration.

BaP Concentration in Water, C*	Corresponding Lifetime Risk Level for 70 kg Person Assuming a 70 Year Lifetime Exposure
30 ng/l [30 x 10^{-6} mg/l]	10^{-5}
3.0 ng/l	10^{-6}
0.3 ng/l	10^{-7}

$$*C \text{ (mg/l)} = 70 \left(\frac{\text{assumed risk level}}{2\ (q_1)}\right)$$

Interpretation and Use of Risk Data

Recognizing that BaP is only one of the PAHs and that direct cancer potency estimation was not feasible in 1980 and 1982 for other PAH compounds, the 1982 Ambient Water Quality Criteria Document Errata for PAH proposed that an assumption be used for PAH mixtures. The assumption was that each PAH compound showing evidence of carcinogenicity be assumed to be as potent as BaP and that, therefore, the carcinogenic effect of a mixture would be proportional to the sum of individual compound concentrations. Using this rationale, the sum of concentrations of all compounds with identifiable carcinogenic evidence is assumed to be equivalent to a like concentration of BaP, and hence, the upper-limit risk of the mixture is assumed to be equal to or less than the risk estimated for BaP.

At this writing, without time to re-evaluate the data base, our recommendation is to utilize the rationale above which is quite similar to that used in developing the 1980 water quality criteria, the differences being a slightly longer list of compounds with carcinogenic evidence which would lengthen the list of compounds for which concentrations are additive, and not using the ingestion of contaminated fish as a factor in human exposure.

Unlike a case where we are concerned about the carcinogenic effect of a single compound, the presence of multiple compounds raises the possibility of co-carcinogenic and related synergistic and/or antagonistic effects. Additionally, there is the fact that many of the PAHs show evidence of mutagenic potential. Since scientifically we are not ready to recommend the best method of quantifying these other hazards from a risk assessment standpoint, the additivity rationale is the only assessment alternative.

The magnitude for overestimation or underestimation of cancer risk using the additive approach is uncertain given the unknowns about PAH mixtures and the risk estimation techniques. On the one hand our lack of knowledge about the mixture's effects on cancer potency, that is our lack of knowledge but suspicion about cocarcinogenicity and other attenuating properties of a mixture and likewise the mutagenic potential of many of the PAH compounds, gives reason not to knowingly underestimate the possible hazards of ingesting PAH mixtures. On the other hand, our preliminary analysis indicates that BaP is one of the more potent of the six compounds, therefore, affording a possibility of over compensation when the additive rationale is used for a broad spectrum mixture. The larger the amount of BaP and/or dibenzo (a,h) anthracene in the mixture the less the possibility for over compensation. Further, it should be recognized that the risk estimation techniques used with the BaP data produce an upper-limit estimate of risk so that the true risks are likely not to exceed this upper limit value.

It must be noted that an epidemiology study of people living near the Reilly Tar Site would provide a more realistic estimate of the risk from this mixture, if the population exposure could be well documented. Such a proposal has been made by the Office of Health and Environmental Assessment (OHEA) and waits approval. Also, to repeat, we do have indications that newer animal data is available regarding the carcinogenicity of PAH compounds, however, time does not permit an examination of these data.

Non Carcinogenic - General Toxicity

In 1980, water quality criteria for fluoranthene and acenaphthene were recommended. The fluoranthene criterion was based upon health considerations while the acenaphthene level was based upon organoleptic considerations (taste and odor).

The fluoranthene criterion concentration, based upon ingesting 2 liters of water per day containing fluoranthene, with an uncertainity factor of 1000, is 0.2 mg/l. This value would be presumed protective of human health until new data is available which would enhance the assessment of the compound's toxicity. The 0.2 mg/l value differs from the 1980 water quality criterion level of 42.0

ug/l because the exposure assumption regarding the ingestion of contaminated fish is not appropriate and hence not used.

The acenaphthene criterion level 0.02 mg/l has no basis in health since sufficient data was not available to adequately evaluate toxicity. The use of this value should be carefully considered since no association with health benefits can be made.

cc: Steven Lutkenhoff
Herman Gibb
Margaret Chu